CDISC 360 status update: starting the journey

Peter Van Reusel, CSO, CDISC
Sam Hume, DSc, VP Data Science, CDISC
3 September 2019
CDISC 360

What is CDISC 360?
Workstreams Overview

WS 1: Create concepts in knowledge graphs

WS 2: Transform concepts in machine readable form

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

API

Extend API's

WS 3: Add transformation semantics

WS 4: Pick and select standards specification

WS 5: Configure study specification and

WS 6: Automatically process and transform data
WS1 Inputs

- 360 Cmap cloud – has initial mapping of one Diabetes TAUG endpoint:
  - Unified concept map (analysis and biomedical concept combo)
  - Split concept map
    - Analysis results map
    - Analysis parameter map
    - Biomedical concept map to SDTM
    - Biomedical concept map to Data Collection

Example of unified concept map
CDISC Library API extension

Knowledge graph

LOAD

Biomedical Concepts
Analysis Concepts
Foundational Standards

Call

Extend Current Set of APIs

API metadata Return

PAA | BBB | X-3 | Y+H | DEF | 1+2 | ...

- Dataset metadata
- Concept metadata
- Concept relations
- Controlled terminology

- Process metadata
- Configuration
- Defaults and options
Use Case 1: End to Start specification
Selecting standards concepts and linked metadata needed for a study
Use Case 2: Start to End Study Metadata

Adding study design, concept configuration & generate artifacts

- Create Operational Database
- Create Tabulation Datasets
- Create ADaM Datasets
- Create Analysis Results structures & shells
- Define Study artifacts
- Study Build and configuration
- Standards Metadata Selection
- Clinical Study Reports
Study Build

Create artifacts (use case 2)

CDISC Library

Configured study metadata

Study builder tool

SDM / XML

Study workflow

Schedule of Activities (SoA)

Study Design

Study Parameters (TS)

Study Parameters (TS)

Study design
- Visits
- Arm’s
- Epochs

- Study parameters (TS)
- Eligibility criteria
- Schedule of activities (SOA)
- Study workflow

Study workflow

Schedule of Activities (SoA)

Run-in Epoch
- First Treatment Epoch
- Second Treatment Epoch
- Follow Up Epoch

Arm A
- Run-in
- A 5 mg
- B 5 mg
- Follow Up

Arm B
- Run-in
- B 5 mg
- A 10 mg
- Follow Up
Use Case 3: Start to End Data Processing

Automatic population of data into artifacts
Project Standards Scope
Diabetes TAUG

Looking for your contribution: Anonymized Diabetes data

- 1 or 2 statistical endpoints
- 3 to 4 ADaM datasets
- 7 to 8 SDTM datasets
- 15 Data Collection Modules
Standards Selection (for the “360 Test Study”)

- 1 or 2 statistical end points
  - Analysis of Glycated Hemoglobin
  - Summary of Hypoglycemic episodes

- ~3-4 ADaM datasets
  - ADSL (Subject-Level Analysis Data (ADSL))
  - Hemoglobin A1C Analysis Dataset (HbA1c Analysis Dataset)
  - Hypoglycemic Episodes Analysis Dataset (Hypoglycemic Episodes Analysis Dataset)
  - Hypoglycemic Episodes Summary Dataset (Hypoglycemic Episodes Summary Dataset)

- ~7-8 SDTM datasets
  - DM (Demographics, to support standard variables in ADSL)
  - VS (Vital Signs, for height and weight in ADSL)
  - CM (Concomitant Meds, to support stratification by background treatment, and for treatments of hypoglycemic events)
  - LB (for Hemoglobin A1C data)
  - CE and FACE (for data on hypoglycemic events)
  - EX, ML (for data about meals and study treatments relative to hypoglycemic events)
  - Trial Design datasets (for arms, visit schedule, definition of hypoglycemic events as disease milestones)

- ~15 CDASH CRFs
  - CDASH CRFs needed to support SDTM datasets above. One CRF will support collection of data about hypoglycemic events that will be mapped to multiple SDTM domains.

For the “360 Test Study” we will, for these standards:
- Develop standard concepts
- Store concepts in prototype CDISC Library
- Pick & select standards from Library (use case 1)
- Configure study spec & create artifacts (use case 2)
- Populate study artifacts with data (use case 3)
CDISC 360
The CDISC 360 journey has started…
## Project Timeline

<table>
<thead>
<tr>
<th>#</th>
<th>Stage</th>
<th>Start</th>
<th>End</th>
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<tbody>
<tr>
<td>1</td>
<td>Initiation, scoping, and internal staffing</td>
<td>Oct 2018</td>
<td>Nov 2019</td>
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<tr>
<td>2</td>
<td>Planning, recruiting CDISC member participants</td>
<td>Dec 2019</td>
<td>Feb 2019</td>
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<tr>
<td>3</td>
<td>Align with Transcelerate Digital Data Flow Initiative</td>
<td>Oct 2018</td>
<td>Jan 2019</td>
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<tr>
<td>3</td>
<td>Onboarding CDISC member participants</td>
<td>Mar 2019</td>
<td>Apr 2019</td>
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<tr>
<td>5</td>
<td>Kickoff, workstreams briefing</td>
<td>Apr 2019</td>
<td>Apr 2019</td>
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<tr>
<td>6</td>
<td>Execution of agile sprints</td>
<td>Apr 2019</td>
<td>Oct 2019</td>
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<tr>
<td>8</td>
<td>Execution of agile sprints</td>
<td>Nov 2019</td>
<td>Mar 2020</td>
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<tr>
<td>9</td>
<td>Project evaluation – Stage 2 (CDISC EU Interchange)</td>
<td>Mar 2020</td>
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<tr>
<td>10</td>
<td>Execution of agile sprints</td>
<td>Apr 2020</td>
<td>Nov 2020</td>
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We are here
CDISC 360 Advisory Committee

CDISC 360 Leadership Team

• David Bobbitt  
  CDISC Chief Executive Officer
• Peter Van Reusel  
  CDISC Chief Standards Officer
• Sam Hume  
  CDISC Vice President Data Sciences
• Barry Cohen  
  CDISC 360 Project Manager

CDISC 360 Board Representation

• Chris Decker - dWise
• Dave Evans - Accenture
• Dave Hardison - Deloitte
• Pandu Kulkarni - Lilly
• Steve Rosenberg - Oracle
• Ulo Palm - * Transcelerate

CDISC 360 Committee Members

• Praveen Garg - Astra Zeneca
• Patrick Genyn - Johnson & Johnson
• Brooke Hinkson - Merck
• Ulo Palm - Allergan
• Mike Hamidi - CDISC
Participation Summary

23 Companies
63 Resources specified

Organization Types:
  • Pharma-Biotech Sponsor: 13
  • CRO: 4
  • Technology Provider: 6
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cdisc

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# Workstream Teams

<table>
<thead>
<tr>
<th>Workstream</th>
<th>Lead</th>
<th>Team Members</th>
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<tbody>
<tr>
<td><strong>WS 1</strong></td>
<td>Bess LeRoy, Jon Neville</td>
<td>Ryan Tubbs, Manuel Anido, John Wang, Erika Liu, Guang-liang Wang, Manjula Reddy, Kathleen Hectors, Joyce George, Nik Pemble, Swanupa Sudini, Sally Cassells, Mikkel Traun, Ryan Tubbs, Smitha Karra, Chithra Subramaniam, Gloria Jones, Pei-Ling Chu</td>
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<td><strong>WS 2</strong></td>
<td>Sam Hume</td>
<td>Francis Dsa, Stephen Pearce, Edward Altman, Haiping Yu, Jeanne Wagner, Erika Liu, Dave Iberson-Hurst, Nicolas de Saint Jorre</td>
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<td><strong>WS 3</strong></td>
<td>Sam Hume</td>
<td>Lex Jansen, Carol Baker, Greg Steffens</td>
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<td><strong>WS 4</strong></td>
<td>Mikkel Traun</td>
<td>Trevor Mankus, Stephen Pearce, Rajesh Modi, Bharat Palakurthi, Lex Jansen, Sujit Khune</td>
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<tr>
<td><strong>WS 5</strong></td>
<td>Tianna Umann, Lauren Shinaberry</td>
<td>Asavari Mehta, Ram Govindaraju, Devi Gohimukkula, Nik Pemble, Rick Rozinskas, Francis Dsa</td>
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<tr>
<td><strong>WS 6</strong></td>
<td>Bhavin Busa</td>
<td>Rick Rozinskas, Julie Smiley, Guang-liang Wang, Gloria Jones, Gina Selby, Naveen Kommuru, Jimmy Zhao, John Brega, Kathleen Hectors, Anoop Ambika, Spandana Chelmilla</td>
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Collaboration Tools

• CDISC 360 Wiki
  • Collaborative content

• Jira
  • Issues management

• CMAP Cloud
  • Concept map development

• Slack
  • Instant messaging

• Technology Platform
  • Use case demo environment
Microsoft & CDISC 360
Collaboration, Development & Proof of Capability Platform

Paul Slater and Ryan Tubbs – Co-founders, Clinical Research Innovation Hub
Kirk Carver, Solution Architect
Tianna Umann PA-C, MA, Solution Architect
Set-up Collaborative Computing platform

• Microsoft will work with CDISC to
  • Set up an Azure Cloud subscription
  • Provide admin rights to the technical team and workstream leads

• Microsoft will deploy and support the following platform services:
  • Azure Active Directory structure - for admin and role based access control
  • Azure Data Lake Storage (ADLS v2) - for meta data storage and data sharing
  • Azure Data Science Virtual Machine - to enable statistical programs (R, Python, etc.)
  • Azure Virtual Machines - to enable applications such as Pinnacle 21 and SAS

➔ CDISC to discuss deployment licenses with Pinnacle 21 and SAS
FDA Use Case

• Use case to include one or more safety analyses for diabetes
  • FDA SMEs to provide exact requirements and definitions
    • May include a commonly used safety analysis and a rarely used safety analysis

• Develop concept maps for the safety analyses as defined by FDA SMEs
  • Use WS1 concept maps as a starting point

• Goal: ensure the standards meet the needs of the reviewer
  • Could be used as a data fitness test to confirm the needed data is present for the safety analyses
  • These templates could be very useful to implementers/sponsors

• FDA is very interested in following the progress of the FHIR, LOINC, and UCUM use cases
WS 1: Create concepts in knowledge graphs.

WS 2: Transform concepts in machine readable form.

WS 3: Add transformation semantics.

WS 4: Identify and select standards specification (Use Case 1).

WS 5: Configure study specification and create artifacts (Use Case 2).

WS 6: Automatically process and transform data (Use Case 3).

WS 7: Document FDA Analysis Requirements in knowledge graphs.

Verify analysis requirements. Verify data & metadata traceability.
Current Activities

• Preparing for the US Interchange
CDISC 360

Expected Outcome
Expected Outcome (1)

• Learn
  • What works and what doesn’t

• Assessment
  • Technology Gap Analysis
  • Standards Gap Analysis

• Building a base for the future
  • Effort calculation
  • Cost / Benefit Analysis
  • Scale up to deliver the standards metadata needed
  • Partnerships with vendors to ensure tools are made available
Expected Outcome (2)

Provide the groundwork/blueprint to:

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<thead>
<tr>
<th>CDISC</th>
<th>Pharma-Biotech</th>
<th>Technology Providers</th>
<th>Regulatory</th>
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<tr>
<td>• Scale up development of concept-based standards definitions for clinical data</td>
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<td>• Continued Development and Curation of CDISC 360 Standards</td>
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<td></td>
<td>• Change environments to automate study build and data processing</td>
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<td>• More focus on sciences, less on repeating tasks</td>
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<td>• Collaborative Data Standards donation to CDISC 360</td>
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<td>• Support Pharma-Biotech organizations by providing tools and solutions that enable end to end automation</td>
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<td></td>
<td></td>
<td>• Communicate to industry its requirements for standardized analyses through CDISC 360 standards</td>
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Thank You!